

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David M. Koelle et al. Examiner: M. Mosher  
Serial No.: To be assigned Group Art Unit: 1648  
Filed: February 11, 2002 Docket: G&C 30967.3-US-D1  
Title: IMMUNOLOGICAL HERPES SIMPLEX VIRUS ANTIGENS AND  
METHODS FOR USE THEREOF

CERTIFICATE OF MAILING UNDER 37 CFR 1.10

'Express Mail' mailing label number: EL 815952662US

Date of Deposit: February 11 2002

I hereby certify that this paper or fee is being deposited with the United States Postal Service 'Express Mail Post Office To Addressee' service under 37 CFR 1.10 and is addressed to: Commissioner for Patents, Washington, D.C. 20231.

By:

*Isabell Ogata*

Name: Isabell Ogata

PRELIMINARY AMENDMENT

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Prior to a first Office Action, please amend the above-identified application as follows:

IN THE SPECIFICATION

Please amend the specification as follows:

This application is a divisional of application serial number 09/368,770, which claims the benefit of United States provisional patent applications 60/095,723 and 60/095,724, both filed on August 7, 1998, the entire contents of which are incorporated herein by reference.

IN THE CLAIMS

Please cancel claims 18-25, 28 and 29 without prejudice to Applicants' right to pursue the subject matter of these claims in another application, amend claims 1, 2, 7, 12, 14 and 27, and add new claims 35-54 as follows:

1. (AMENDED) A pharmaceutical composition comprising an isolated herpes simplex virus (HSV) polypeptide, wherein the polypeptide comprises a U<sub>L</sub>19, U<sub>L</sub>21, or U<sub>L</sub>49 protein, and a pharmaceutically acceptable carrier.
2. (AMENDED) A pharmaceutical composition comprising an isolated HSV polypeptide and a pharmaceutically acceptable carrier, wherein the polypeptide comprises an amino acid sequence selected from the group consisting of:
  - (a) amino acids 1078-1319 of U<sub>L</sub>19;
  - (b) amino acids 148-181 of U<sub>L</sub>21;
  - (c) amino acids 105-190 or 177-220 of U<sub>L</sub>49;
  - (d) amino acids 1-273 of glycoprotein E (gE); and
  - (e) amino acids 185-197 or 209-221 of VP16; and
3. The composition of claim 1, wherein the polypeptide is a fusion protein.
4. The composition of claim 3, wherein the fusion protein is soluble.
5. The composition of claim 2, wherein the polypeptide is a fusion protein.
6. The composition of claim 5, wherein the fusion protein is soluble.
7. (AMENDED) A polynucleotide that encodes a polypeptide comprising an amino acid sequence consisting essentially of:
  - (a) amino acids 1078-1319 of U<sub>L</sub>19;
  - (b) amino acids 148-181 of U<sub>L</sub>21;
  - (c) amino acids 105-190 or 177-220 of U<sub>L</sub>49;
  - (d) amino acids 1-273 of glycoprotein E (gE); or
  - (e) amino acids 185-197 or 209-221 of VP16.

8. A vector comprising the polynucleotide of claim 7.
9. A host cell transformed with the vector of claim 8.
10. A method of producing an HSV polypeptide comprising culturing the host cell of claim 9 and recovering the polypeptide so produced.
11. An HSV polypeptide produced by the method of claim 10.
12. (AMENDED) A pharmaceutical composition comprising a polynucleotide that encodes an HSV polypeptide, wherein the polypeptide comprises a U<sub>L</sub>19, U<sub>L</sub>21, or U<sub>L</sub>49 protein, and a pharmaceutically acceptable carrier.
13. A pharmaceutical composition comprising the polynucleotide of claim 7 and a pharmaceutically acceptable carrier.
14. (AMENDED) A recombinant virus genetically modified to express a U<sub>L</sub>19, U<sub>L</sub>21, or U<sub>L</sub>49 protein.
15. A recombinant virus genetically modified to express the polypeptide of claim 11.
16. The recombinant virus of claim 14 which is a vaccinia virus, canary pox virus, lentivirus, retrovirus, herpes virus or adenovirus.
17. A pharmaceutical composition comprising the virus of claim 16 and a pharmaceutically acceptable carrier.
26. A method of treating or preventing an HSV infection in a subject comprising administering the composition of claim 1 to the subject.
27. (AMENDED) A method of treating or preventing an HSV infection in a subject comprising administering the pharmaceutical composition of claim 2 to the subject.
30. The pharmaceutical composition of claim 1, further comprising an adjuvant.
31. The pharmaceutical composition of claim 2, further comprising an adjuvant.

32. The pharmaceutical composition of claim 12, further comprising an adjuvant.
33. The pharmaceutical composition of claim 13, further comprising an adjuvant.
34. The pharmaceutical composition of claim 17, further comprising an adjuvant.
35. (NEW) A method of enhancing proliferation of HSV-specific T cells comprising contacting the HSV-specific T cells with an isolated polypeptide that comprises an immunogenic fragment of U<sub>L</sub>19, U<sub>L</sub>21, U<sub>L</sub>49, glycoprotein E (gE) or VP16.
36. (NEW) The method of claim 35, wherein the immunogenic fragment comprises amino acids 1078-1319 of U<sub>L</sub>19; 148-181 of U<sub>L</sub>21; 105-190 or 177-220 of U<sub>L</sub>49; 1-273 of glycoprotein E (gE); or 185-197 or 209-221 of VP16.
37. (NEW) A method of enhancing the production of HSV-specific antibodies in a subject comprising administering to the subject an isolated polypeptide that comprises an immunogenic fragment of U<sub>L</sub>19, U<sub>L</sub>21, U<sub>L</sub>49, glycoprotein E (gE) or VP16.
38. (NEW) The method of claim 37, wherein the immunogenic fragment comprises amino acids 1078-1319 of U<sub>L</sub>19; 148-181 of U<sub>L</sub>21; 105-190 or 177-220 of U<sub>L</sub>49; 1-273 of glycoprotein E (gE); or 185-197 or 209-221 of VP16.
39. (NEW) A recombinant non-HSV virus genetically modified to express a U<sub>L</sub>19, U<sub>L</sub>21, or U<sub>L</sub>49 protein.
40. (NEW) The recombinant non-HSV virus of claim 39 which is a vaccinia virus, canary pox virus, lentivirus, retrovirus, herpes virus or adenovirus.
41. (NEW) A pharmaceutical composition comprising the non-HSV virus of claim 39 and a pharmaceutically acceptable carrier, wherein the virus is a vaccinia virus or a canary pox virus.
42. (NEW) The pharmaceutical composition of claim 41, further comprising an adjuvant.

43. (NEW) A fusion protein comprising an HSV polypeptide fused to a heterologous polypeptide, wherein the HSV polypeptide consists essentially of amino acids 1078-1319 of U<sub>L</sub>19; 148-181 of U<sub>L</sub>21; 105-190 or 177-220 of U<sub>L</sub>49; 1-273 of glycoprotein E (gE); or 185-197 or 209-221 of VP16.
44. (NEW) A fusion protein of claim 43 that is soluble.
45. (NEW) A polynucleotide that encodes a fusion protein of claim 43.
46. (NEW) A vector comprising the polynucleotide of claim 45.
47. (NEW) A host cell transformed with the vector of claim 46.
48. (NEW) A method of producing a fusion protein comprising culturing the host cell of claim 47 and recovering the fusion protein so produced.
49. (NEW) A fusion protein produced by the method of claim 48.
50. (NEW) A fusion protein of claim 49 that is soluble.
51. (NEW) A pharmaceutical composition comprising the fusion protein of claim 43, and a pharmaceutically acceptable carrier.
52. (NEW) The pharmaceutical composition of claim 51, further comprising an adjuvant.
53. (NEW) A pharmaceutical composition comprising the fusion protein of claim 49, and a pharmaceutically acceptable carrier.
54. (NEW) The pharmaceutical composition of claim 53, further comprising an adjuvant.

REMARKS

Prior to a first Office Action in this application, Applicants request that claims 18-25, 28 and 29 be canceled, original claims 1, 2, 7, 12, 14 and 27 be amended, and new claims 35-54 be added.

These amendments and new claims do not involve new matter or objectionable changes. When the Examiner takes this application up for action, entry of these amendments is respectfully requested.

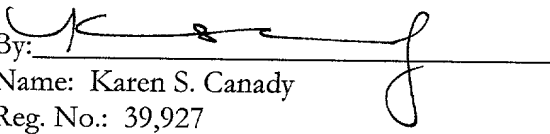
It is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

GATES & COOPER LLP  
Attorneys for Applicant(s)

Howard Hughes Center  
6701 Center Drive West, Suite 1050  
Los Angeles, California 90045  
(310) 641-8797

Date: February 11, 2002

By:   
Name: Karen S. Canady  
Reg. No.: 39,927

KSC/io

G&C 30967.3-US-D1

APPENDIX: SPECIFICATION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Please amend the specification as follows:

This application is a divisional of application serial number 09/368,770, which claims the benefit of United States provisional patent applications 60/095,723 and 60/095,724, both filed on August 7, 1998, the entire contents of which are incorporated herein by reference.

## APPENDIX: CLAIMS WITH MARKINGS TO SHOW CHANGES MADE

### IN THE CLAIMS

Please amend claims 1, 2, 7, 12, 14 and 27 as follows:

1. (AMENDED) A pharmaceutical composition comprising an isolated herpes simplex virus (HSV) polypeptide, wherein the polypeptide comprises a U<sub>L</sub>19, U<sub>L</sub>21, or U<sub>L</sub>49 [or U<sub>L</sub>50] protein [or a fragment thereof], and a pharmaceutically acceptable carrier.
2. (AMENDED) A pharmaceutical composition comprising an isolated HSV polypeptide and a pharmaceutically acceptable carrier, wherein the polypeptide comprises an amino acid sequence selected from the group consisting of:
  - (a) amino acids 1078-1319 of U<sub>L</sub>19;
  - (b) amino acids 148-181 of U<sub>L</sub>21;
  - (c) amino acids 105-190 or 177-220 of U<sub>L</sub>49;
  - [(d) amino acids 118-312 of U<sub>L</sub>50;]
  - [(e)] (d) amino acids 1-273 of glycoprotein E (gE); and
  - [(f)] (e) amino acids 185-197 or 209-221 of VP16; and
  - [(g) substitutional variants of (a)-(f)].
7. (AMENDED) A polynucleotide that encodes a polypeptide comprising an amino acid sequence [selected from the group] consisting essentially of:
  - (a) amino acids 1078-1319 of U<sub>L</sub>19;
  - (b) amino acids 148-181 of U<sub>L</sub>21;
  - (c) amino acids 105-190 or 177-220 of U<sub>L</sub>49;
  - [(d) amino acids 118-312 of U<sub>L</sub>50;]



[(e)] (d) amino acids 1-273 of glycoprotein E (gE); or

[(f)] (e) amino acids 185-197 or 209-221 of VP16; and

substitutional variants of (a)-(f).

12. (AMENDED) A pharmaceutical composition comprising a polynucleotide that encodes an HSV polypeptide, wherein the polypeptide comprises a U<sub>L</sub>19, U<sub>L</sub>21, or U<sub>L</sub>49 [or U<sub>L</sub>50] protein [or a fragment thereof], and a pharmaceutically acceptable carrier.
14. (AMENDED) A recombinant virus genetically modified to express a U<sub>L</sub>19, U<sub>L</sub>21, or U<sub>L</sub>49 [or U<sub>L</sub>50] protein [or a fragment thereof].
27. (AMENDED) A method of treating or preventing an HSV infection in a subject comprising administering the [immune cell of claim 21] pharmaceutical composition of claim 2 to the subject.